

# Federal Guidelines for Opioid Treatment

Spring Training Institute  
Missouri Department of Mental Health  
May 29, 2003

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Center for Substance Abuse Treatment  
Substance Abuse and Mental Health  
Services Administration



# Opioid Assisted Treatment

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- Opioid Treatment Programs
  - Program Based
  - Office Physician Based
  - Emerging issues
- Partial Opioid (buprenorphine)
  - New Legislation
  - Implementation
  - Emerging Issues

# Current Inventory of Regulated OTPs



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- 1,000-1,200 Opioid Treatment Programs (OTPs)
  - Certified by SAMHSA/CSAT
  - Registered by DEA
  - Licensed by State
- 950 Maintenance, 250 Detoxification
- approximately 205,000 Patients in Treatment

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# Regulatory Oversight

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- Detailed Federal regulations developed in 1970's to:
  - Assure quality treatment
  - Reduce risk of medication diversion
- Detailed Process Oriented, Proscriptive Rule
- Regulatory Compliance Inspections

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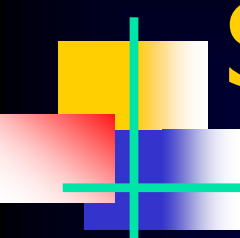


# Opioid Treatment Reform

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- HIV and IVDU
- Availability of treatment
  - Waiting list
  - Inability to open new programs
  - “Treatment Gap”
- Quality of treatment
- Over regulation

# Federal Opioid Treatment Standards (§8.12)



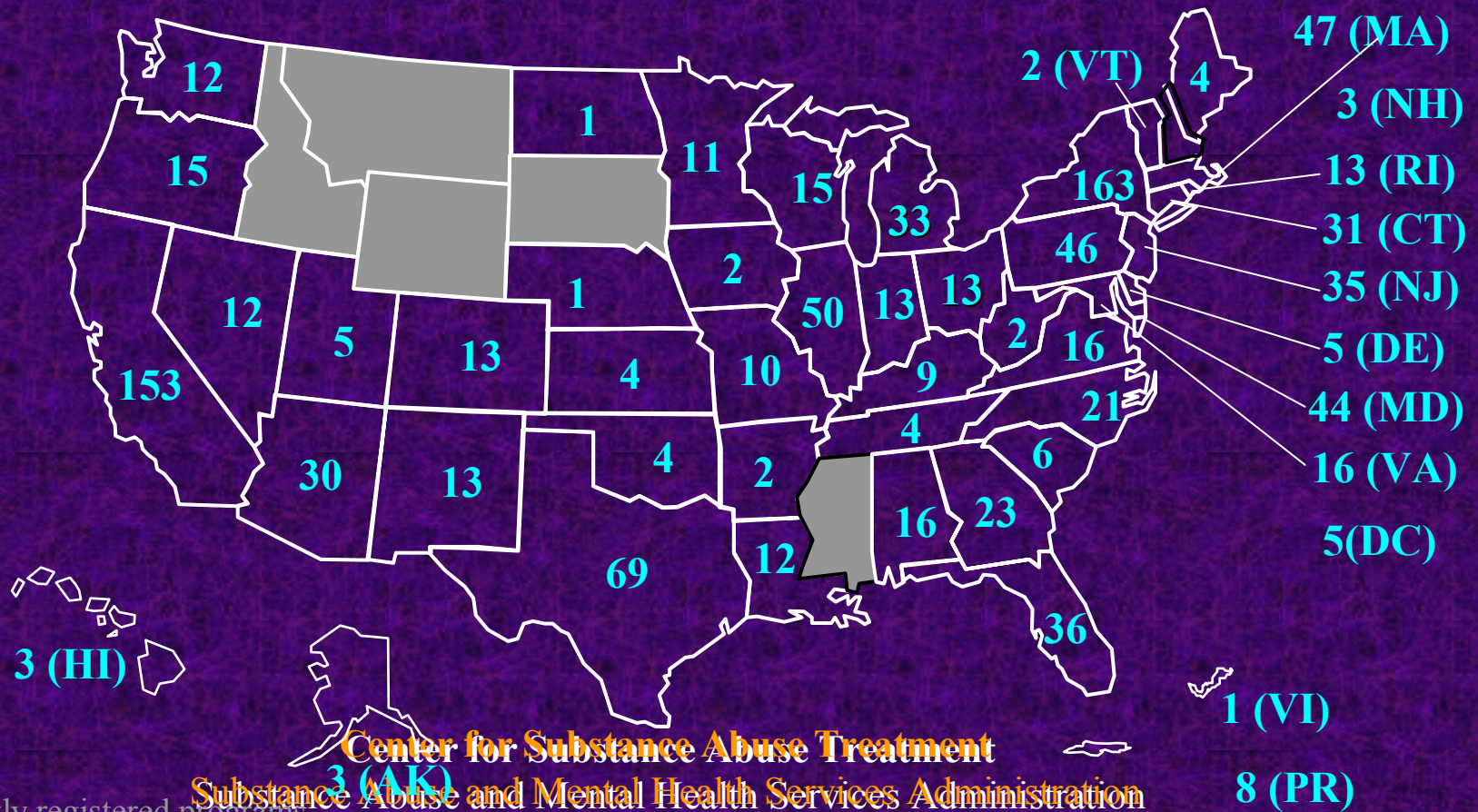
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- Administrative and organizational structure
- Quality assurance/improvement
- Diversion Control Plan
- Staff credentials
- Patient admission criteria
- Required services
- Record keeping and patient confidentiality
- Medication administration, dispensing
- Unsupervised use
- Interim maintenance
- Detoxification

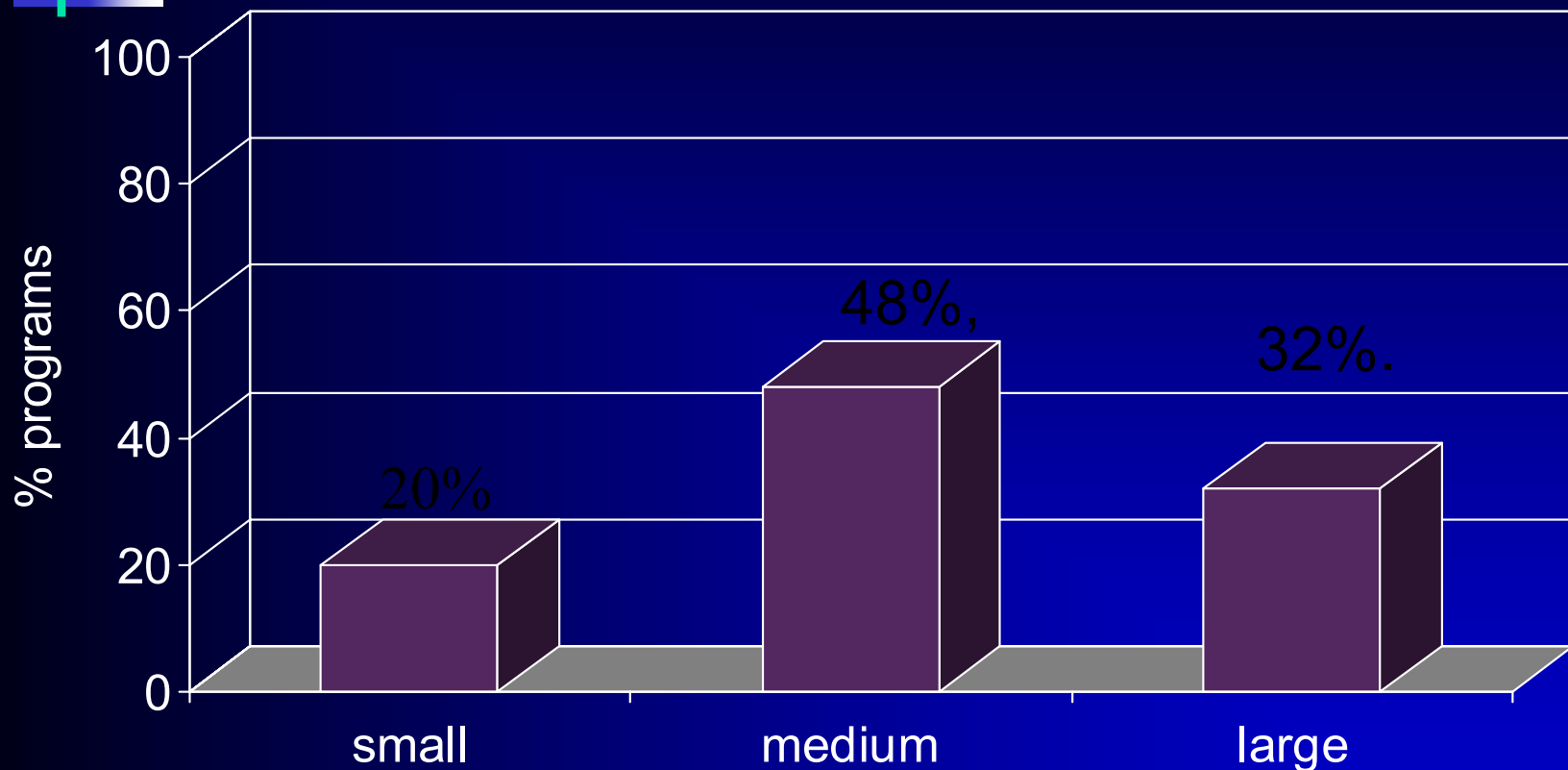
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# ACTIVE OTPs IN THE U.S.

(Total by State including Washington, D.C., Puerto Rico, and US Virgin Islands)



# OTP Size – Number of Patients Enrolled



**Mean = 253**

**Range: 20 to 1000+ patients**

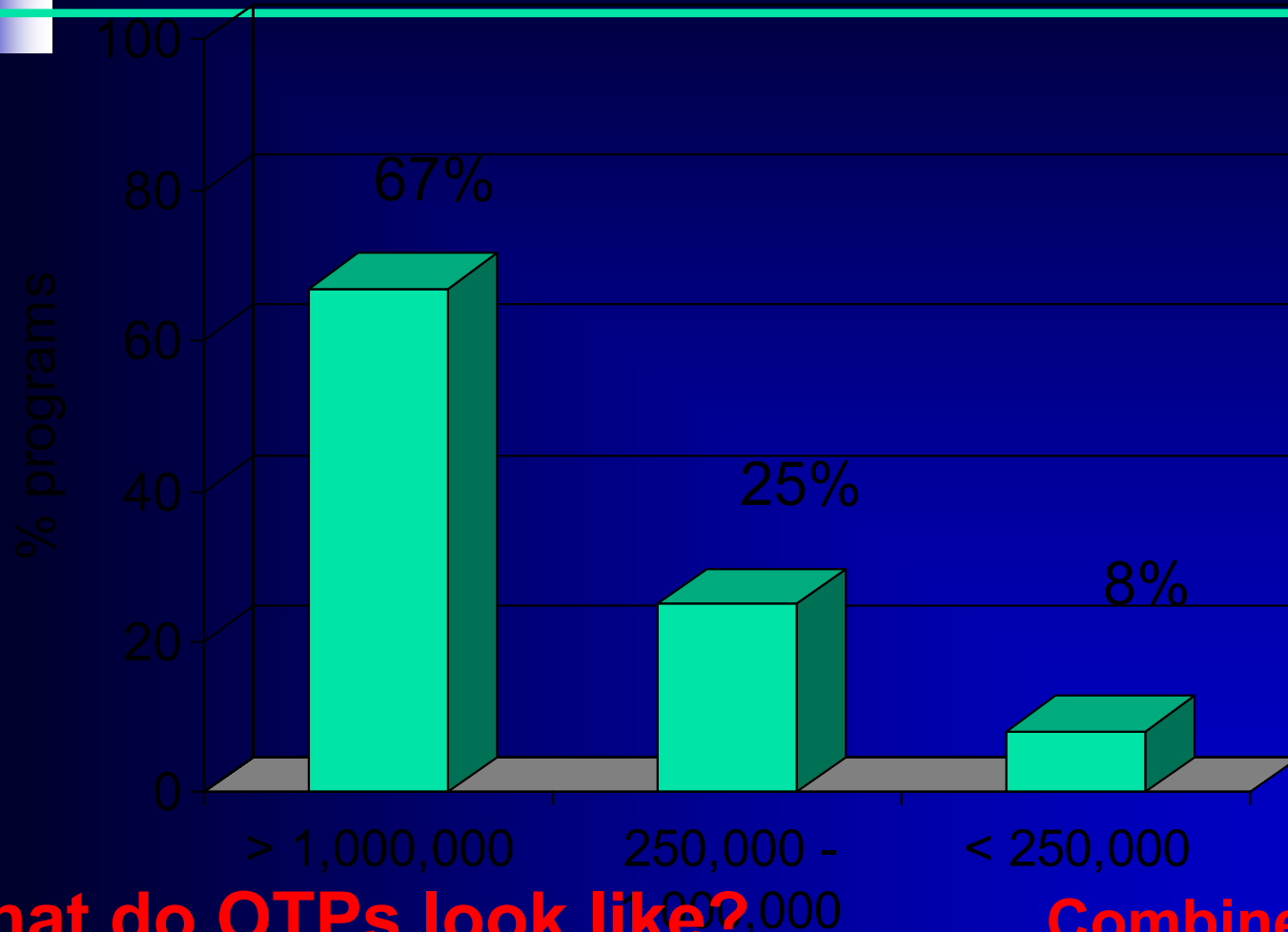
**What do OTPs look like? Combined**

**Sample** Center for Substance Abuse Treatment

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# OTP Location



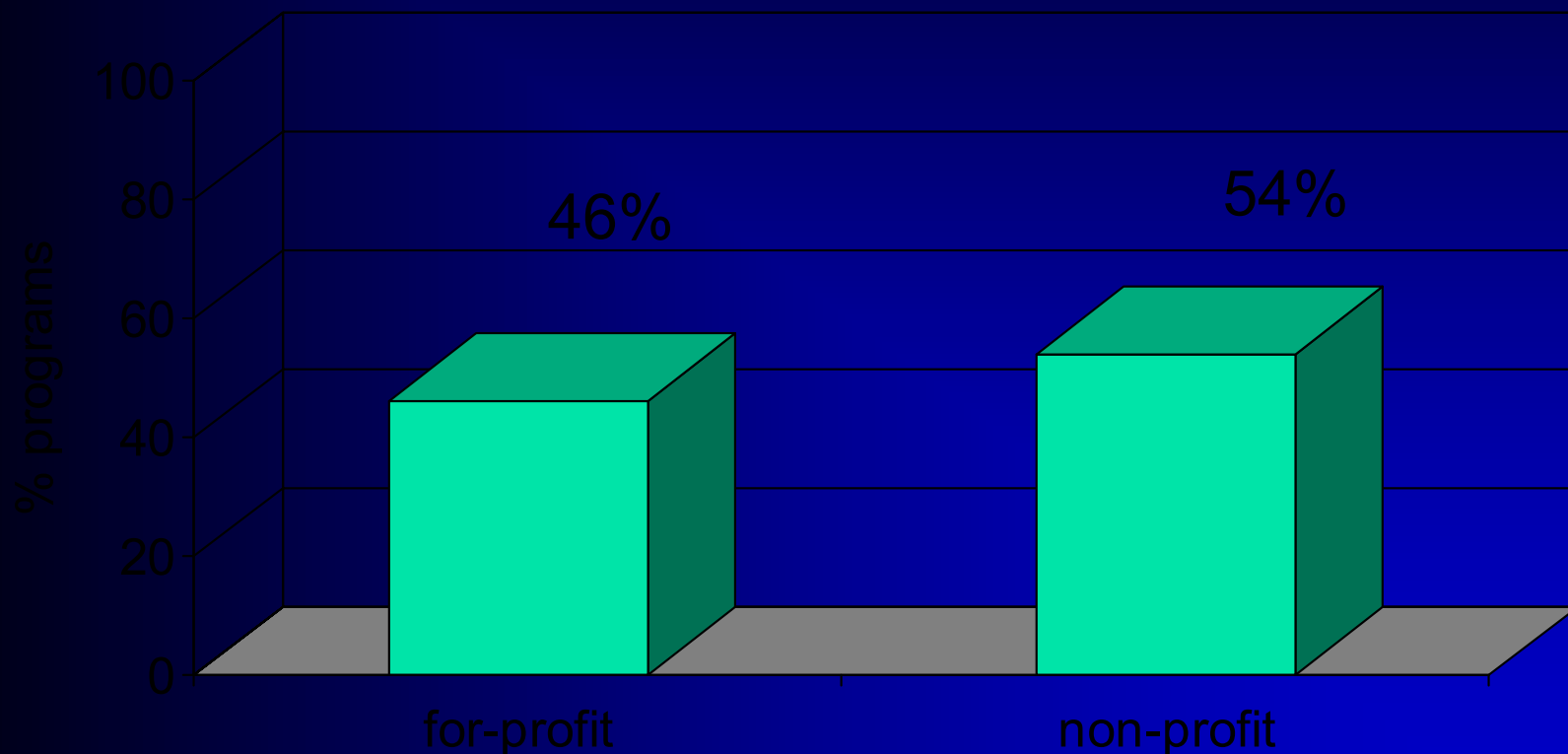
**What do OTPs look like?**

**Sample**

**Combined**

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# OTP Ownership



**What do OTPs look like?**

**Combined**

**Sample**

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# Other Program Characteristics

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- Multi-site: 70% are a unit of a larger entity
- Staff size: average 11 direct care staff
- Staffing ratio: average 42 patients per counselor

**What do OTPs look like?**

**Combined**

**Sample**

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# Treatment Status

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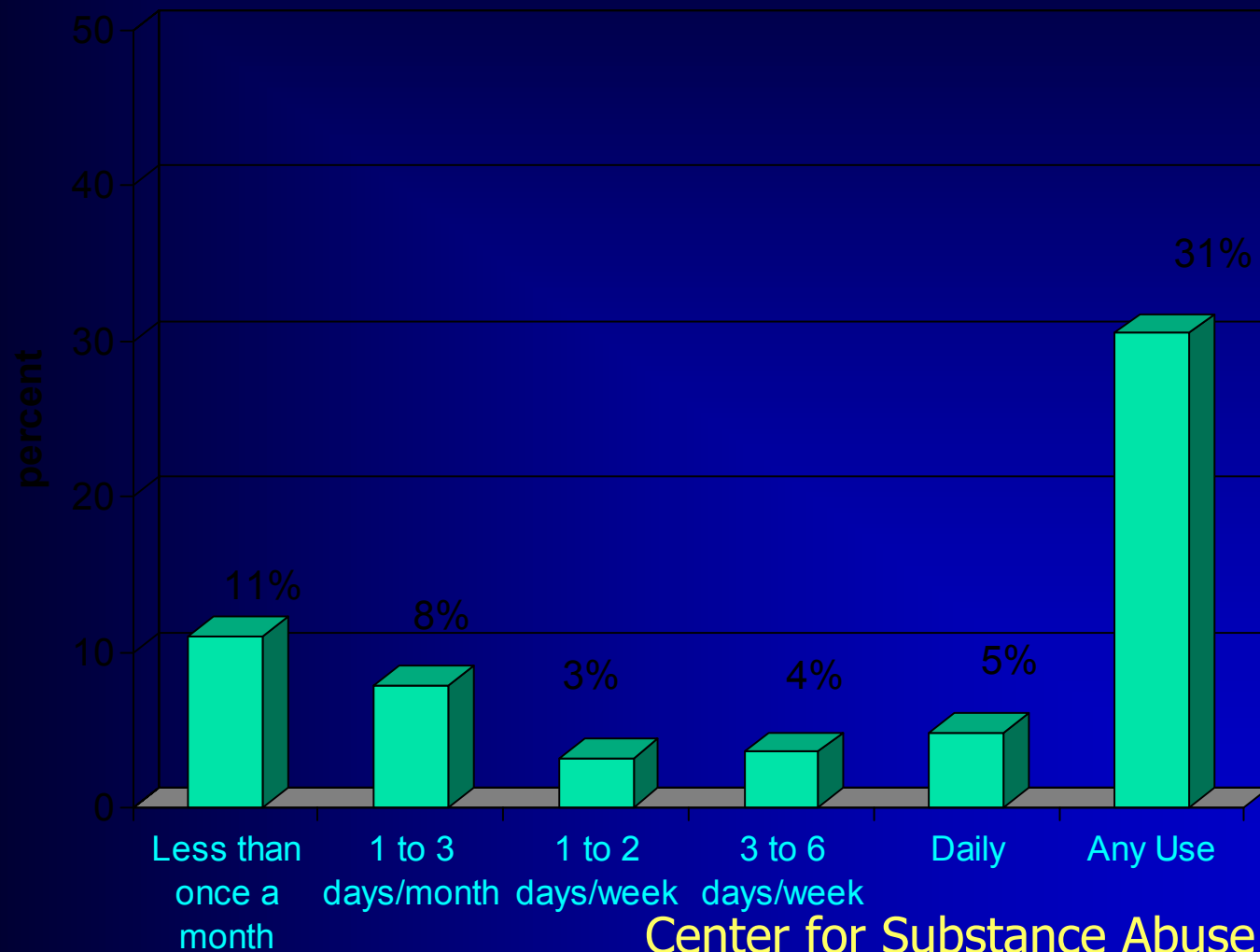
## Length of time in continuous treatment at clinic

0 to 3 months	14%
4 to 6 months	10%
7 to 12 months	13%
13 to 24 months	22%
<i>More than 24 months</i>	<i>41%</i>

Has had methadone/LAAM  
treatment before **58%**

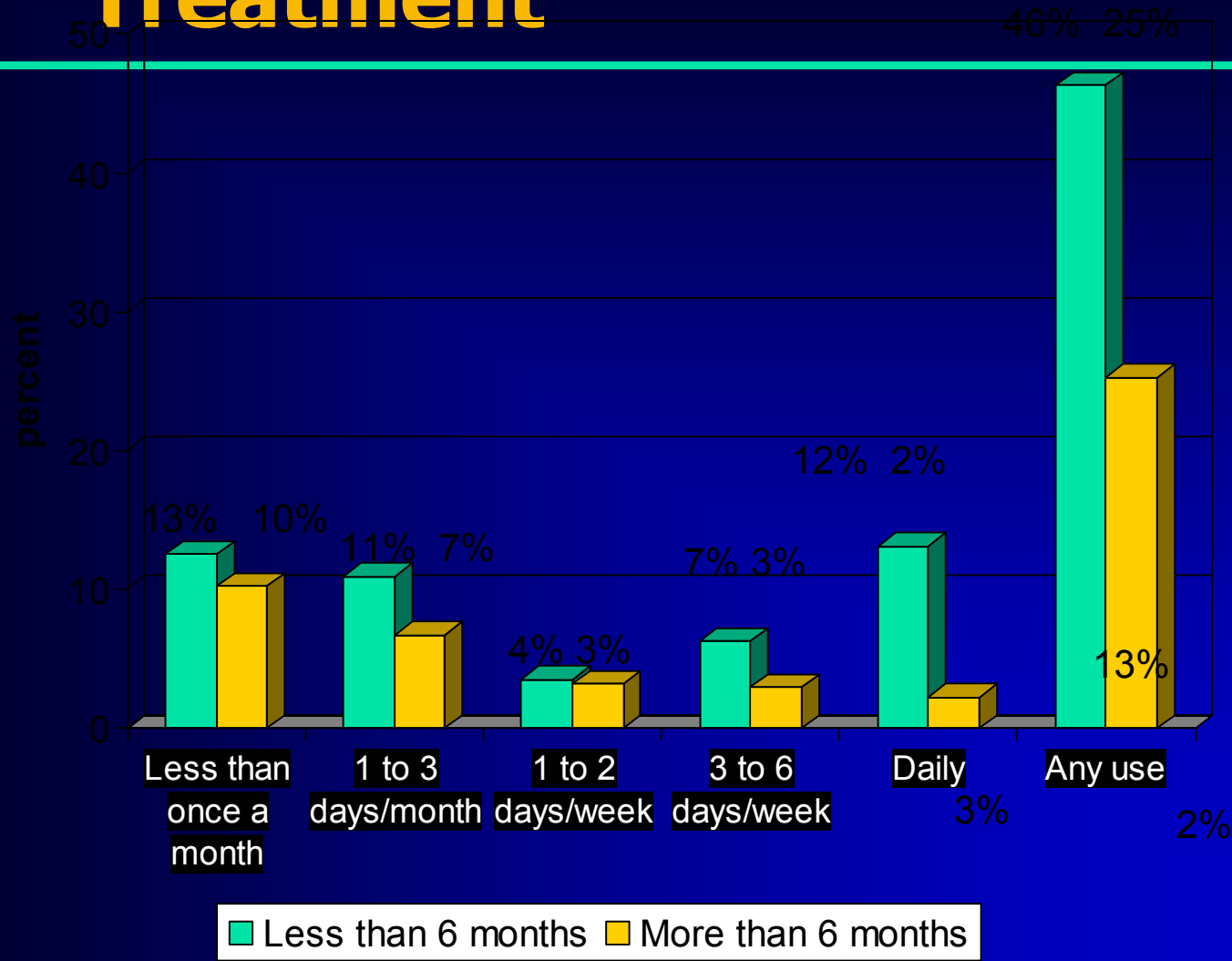
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# Heroin Use, Past Three Months



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Anonymous Self Report

# Heroin Use, by Time in Treatment



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 Anonymous Self Report



# Total Cost per Patient Per Year

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## Costs per Patient

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<b>All Sites (N=170)</b>	<b>\$4,176</b>
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### By Ownership Status

<b>Nonprofit/public (N=100)</b>	<b>\$4,580</b>
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<b>For-Profit (N=70)</b>	<b>\$3,713</b>
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### By Site Size

<b>1 to 100 patients (N=34)</b>	<b>\$5,216</b>
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<b>101 to 300 patients (N=83)</b>	<b>\$3,996</b>
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<b>&gt;300 patients (N=53)</b>	<b>\$3,812</b>
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### By Organization Structure

<b>Multi-Site Organization</b>	<b>\$4,575</b>
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<b>(N=120)</b>	
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<b>Single-Site Organization</b>	<b>\$3,229</b>
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<b>(N=50)</b>	
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# Regulatory Reform

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- New Tx Regulations
- Required Services
  - Counseling, medication
  - Medication dispensing
  - Drug abuse testing





# Regulatory Reform

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- Accreditation – Phase III-Active Accreditation by 5/03 to 5/04
  - 40% accredited
  - 45% in process
  - 15% uncertain status
- JCAHO, CARF, COA, Washington, Missouri
  - Contact with DEA
  - Contact with State Regulatory Authorities

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# Certification

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- The SMA-162 Form should be used for provisional certification, new sponsor, new medical director, relocation, medication unit and renewal.
- When applying for provisional certification, be sure to address the attachments A-H listed on the checklist.
- Submit Accreditation Application
- You can download the SMA-162, and checklist from our website, [www.dpt.samhsa.gov](http://www.dpt.samhsa.gov)

# SMA-162 Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION CENTER FOR SUBSTANCE ABUSE TREATMENT		Form Approved OMB Number 0930-0206 Expiration Date: 09/30/2003 See OMB Statement on Reverse										
<b>Application for Certification to Use Opioid Drugs          in a Treatment Program Under 42 CFR § 8.11</b>		DATE OF SUBMISSION										
<b>Note:</b> This form is required by 42 CFR 8.11 pursuant to Sec. 303, Controlled Substances Act (21 USC § 823) and the Drug Abuse Prevention and Control Act of 1970 (42 USC § 275(a)). Failure to report may result in a recommendation for the suspension or revocation of the opioid treatment program registration.												
<b>1a. NAME OF PROGRAM</b> <i>(Name of primary dispensing location)</i>												
<b>b. Opioid Treatment Program Number (OTP Number):</b> <i>(same as FDA ID)</i>		<b>c. DEA Registration Number</b>										
<b>2. ADDRESS OF PRIMARY DISPENSING LOCATION</b> <i>(Include Zip Code)</i>		<b>3. TELEPHONE NUMBER</b> <i>(Include Area Code)</i>										
		<b>4. FAX NUMBER</b> <i>(Include Area Code)</i>										
<b>5. NAME AND ADDRESS OF PROGRAM SPONSOR</b> <i>(Include Zip Code)</i>		<b>6. TELEPHONE NUMBER</b> <i>(Include Area Code)</i>										
		<b>7. FAX NUMBER</b> <i>(Include Area Code)</i>										
		<b>8. E-MAIL ADDRESS</b>										
<b>9. PURPOSE OF APPLICATION</b> Provisional Certification <input type="checkbox"/> New Sponsor <input type="checkbox"/> New Medical Director <input type="checkbox"/> Relocation <input type="checkbox"/> Medication Unit <input type="checkbox"/> Renewal <input type="checkbox"/>												
<b>10. NUMBER OF PATIENTS IN TREATMENT ON DATE OF SUBMISSION:</b> METHADONE    LEVO-ALPHA-ACETYL-METHADOL (LAAM)    OTHER <i>(Specify)</i>												
<b>11. PROGRAM FUNDING SOURCES</b> <i>(Check each appropriate agency and attach the address of each, if applicable.)</i> <table border="0"> <tr> <td><input type="checkbox"/> SAMHSA (Block Grant)</td> <td><input type="checkbox"/> Private Charities</td> <td><input type="checkbox"/> Department Of Veterans Affairs</td> </tr> <tr> <td><input type="checkbox"/> Patient Payment</td> <td><input type="checkbox"/> State Government</td> <td><input type="checkbox"/> City &amp; County Government</td> </tr> <tr> <td><input type="checkbox"/> Indian Health Service</td> <td><input type="checkbox"/> Private Health Insurance</td> <td><input type="checkbox"/> Other <i>(Specify)</i> _____</td> </tr> </table>				<input type="checkbox"/> SAMHSA (Block Grant)	<input type="checkbox"/> Private Charities	<input type="checkbox"/> Department Of Veterans Affairs	<input type="checkbox"/> Patient Payment	<input type="checkbox"/> State Government	<input type="checkbox"/> City & County Government	<input type="checkbox"/> Indian Health Service	<input type="checkbox"/> Private Health Insurance	<input type="checkbox"/> Other <i>(Specify)</i> _____
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<b>12. Application</b> Substance Abuse and Mental Health Services Administration Division of Pharmacologic Therapies Attention: OTP Certification Program Rockwall II Building, Suite 740 5600 Fishers Lane Rockville, MD 20857  Dear Sir/Madam:  As the person responsible for the program (OTP), I submit this application in triplicate for approval to use approved opioid drugs in a program for detoxification and/or maintenance treatment for narcotic addicts in accordance with 42 CFR Part 8, Certification of Opioid Treatment Programs. A copy of this application has been sent to the State Authority within which State the program is located. I understand that SAMHSA and State approvals are necessary to obtain a registration from the Drug Enforcement Administration (DEA).  A. I have a copy of, or access to 42 CFR Part 8, Certification of Opioid Treatment Programs, including 42 CFR § 8.12, the Federal Opioid Treatment Standards. I have read, understand and will comply with these standards which govern the treatment of narcotic addiction with approved opioid drugs.  B. Attached is a description of the current accreditation status of the OTP. This description includes the name and address of the accreditation body and the date of the last accreditation action.  C. Attached is a description of the organizational structure of the OTP which includes the name and complete address of any central administration or larger organizational structure to which this program is responsible. The description shall specify how the program will provide adequate medical, counseling, vocational, educational, and assessment services, at the primary facility, unless the program sponsor has entered into a formal documented agreement with another entity to provide these services to patients enrolled in the OTP. In addition, the attachment includes the names of the persons responsible for the OTP.		D. Attached are the names, addresses, and a description of each hospital, institution, clinical laboratory, or other facility used by this program to provide the necessary medical and rehabilitative services.  E. A medical director will be designated to assume responsibility for administering all medical services performed by the program. If a medical director is responsible for more than one program, the feasibility of such an arrangement will be documented and submitted to SAMHSA. Within three weeks of any replacement of the medical director, I shall notify SAMHSA.  F. Attached is the address of each medication unit or other facility under control of the OTP. Any new dispensing site for this program, including medication units shall be approved by SAMHSA and the State authority prior to its use. SAMHSA and the State authority shall be notified within three weeks of the deletion of any facility used to dispense opioid treatment drugs.  G. A patient records system will be established and maintained to document and monitor patient care in this program. It shall be maintained so as to comply with the Federal and State reporting requirements relevant to narcotic treatment. A drug dispensing record will be maintained to show dates, quantity, and batch or code marks of the drug administered or dispensed, traceable to specific patients. This drug dispensing record must be retained for a period of three years from the date of dispensing.  H. I have a copy of, or access to 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records. I have read and understand the requirements to maintain the confidentiality of alcohol and drug abuse treatment patient records. I agree to protect the identity of all patients in accordance with the regulations.										

FORM SMA-162 (revised 2002) (FRONT) *(Submit in triplicate)*

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# Steps to Certification

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- ① Notify State, DEA & CSAT's Division of Pharmacologic Therapies (DPT)
- ② DEA Pre-Registration Inspection
- ③ State Review & Recommendations
- ④ Concurrent DEA, State, & CSAT Approval
- ⑤ Receive Provisional Certification

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# OBOT/Medical Maintenance

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- Studied for over a decade
- 700 patients
- Tremendous benefit to many, but not all patients
- Continuum of care
- Expected to increase dramatically in the near future.



# Methadone OBOT - July 1999 Proposal

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- Concept of “office-based opioid treatment” and requested comments
  - How to modify Federal opioid treatment standards to accommodate office-based treatment?
  - Should separate OBOT standards be developed for this rule?



# Final Rule Consideration

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- Separate standards would lead to “two tiered system”
- Insufficient information to develop separate OBOT standards
- Concern about untrained physicians

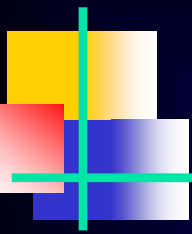


# Final Rule Consideration *cont.*

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- Experiences in other countries
- DEA regulations prohibit Rx
- State regulations changes
- Recommendations for expanded “medical maintenance”





# Considerations and Issues

## *Methadone OBOT*

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- Treatment provided
  - OTP with reduced patient attendance
  - Affiliated/linked physician's office
  - Free-standing physician
- OBOT Patients
  - Stabilized
  - New to treatment



# Considerations and Issues

*Methadone OBOT*

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- Medication Dispensation
  - OTP
  - Physicians office
  - Community pharmacy



# OBOT/Medical Maintenance

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- **Medical Maintenance - 14-30 day take-homes-bimonthly/monthly reporting.**
- **Medical Maintenance w/ off site physician affiliated with an OTP, treating stabilized patients (10 approved)**
- **Medical Maintenance w/ off site physician and pharmacy dispensing (2 approved) solid med.**
- **Office-based treatment w/non stabilized pts, non affiliated physicians (0 approved)**



# Opioid Assisted Treatment

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## ■ Buprenorphine

- New Legislation – On May 22, SAMHSA announced an interim final rule allowing opioid treatment programs (OTPs) to offer buprenorphine treatment along with methadone and ORLAAM.
- The rule enables OTPs that are certified by SAMHSA to use newly approved buprenorphine products, Subutex and Suboxone for maintenance or detoxification treatment of dependence on opioids such as heroin or prescription pain relievers.
- The rule went into effect May 22, 2003 with a comment period open for 60 days, until July 21, 2003

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# Methadone Mortality

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- New York Times - National Desk  
February 9, 2003, Sunday
  - "Methadone, Once the Way Out, Suddenly Grows as a Killer Drug"
  - "Methadone, a drug long valued for treating heroin addiction and for soothing chronic pain, is increasingly being abused by recreational drug users and is causing an alarming rise in overdoses and deaths, federal and state officials say."

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# Methadone Mortality —Wash Times

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- EDITORIAL February 19, 2003
- **“Medicine or menace?”**
  - People are overdosing on methadone in record numbers. Nearly 11,000 people appeared in emergency rooms following methadone overdoses in 2001,
  - Double the number from 1999, according DAWN.

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# Washington Times, (cont.)

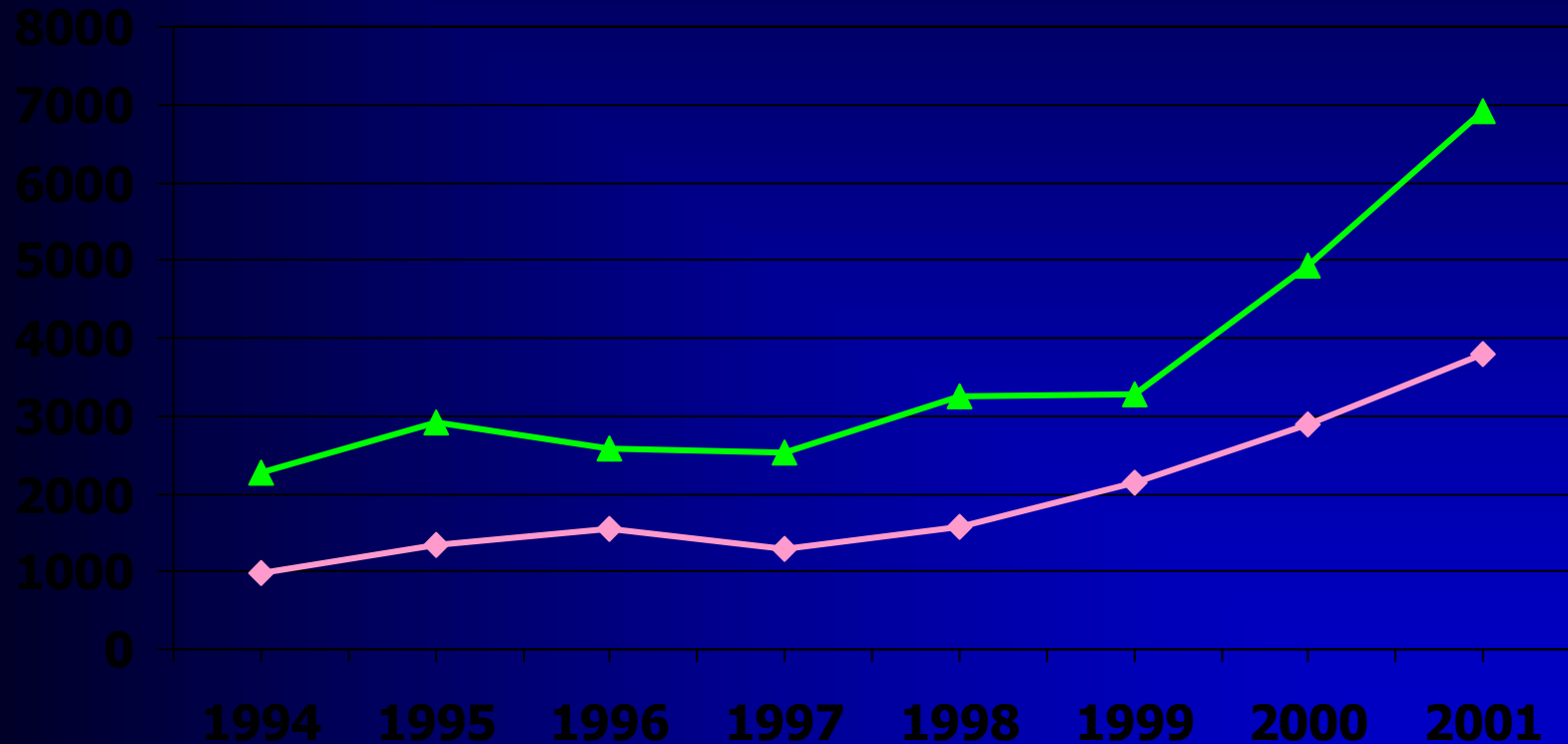
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- “The increases might be related to a loosening of federal guidelines in 2001, which allow substance abusers who already have earned a sufficient level of trust while in treatment to take home up to 31 days of methadone doses.
- However, the drug is much more easily procured as a prescription painkiller.
- When methadone is prescribed as a painkiller, the doses are higher since the drug's ability to numb pain is smaller than its ability to reduce heroin cravings.”

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# Methadone-related ED visits, U.S.

ED visits

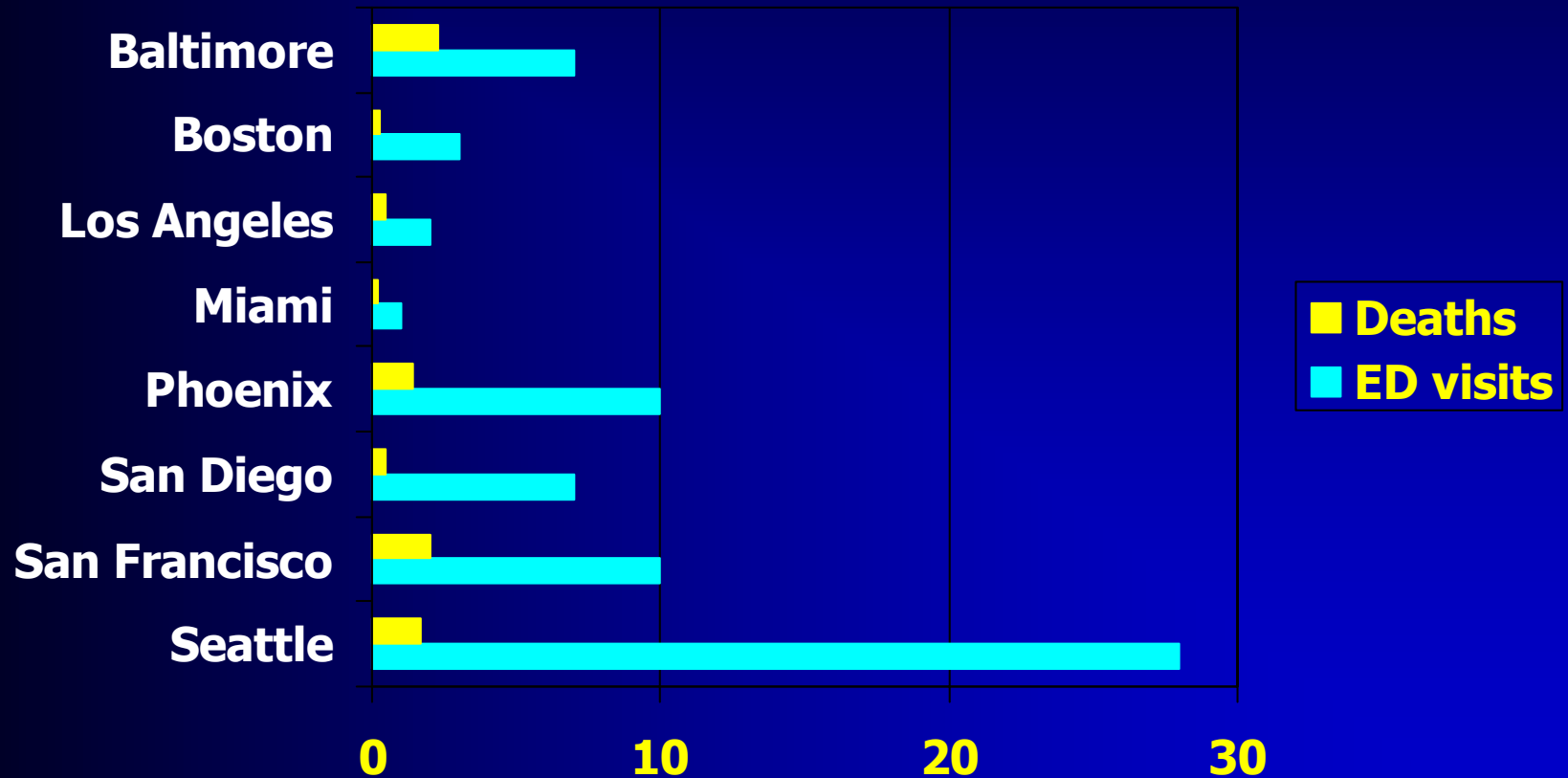


—◆— One-drug —▲— Polydrug

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# Rates for methadone-related ED visits and deaths, 2001



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# DAWN Conclusions

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- Few deaths attributed to methadone alone
- No consistent pattern across metro areas
- Increases in methadone ED mentions not necessarily associated with deaths
- Most methadone ED visits because of dependence



# DAWN Conclusions, cont.

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- Methadone needs to be seen in context of narcotic analgesic abuse
- Other narcotic analgesics have shown greater increases in ED visits
- DAWN will continue to monitor methadone



# May 8-9 Methadone Associated Mortality Workgroup

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- Regulators, Law Enforcement
- Epidemiologists, ME, Forensic
- Pain and Addiction Treatment
- Increased/improved monitoring and surveillance
- Increased education of healthcare disciplines
- Comprehensive Report

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# Conclusions

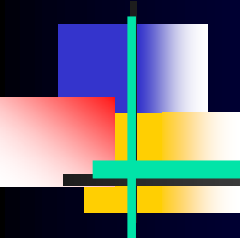
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- Abuse of heroin and prescription opiates continues to increase.
- Opioid treatment available in new forms
  - Buprenorphine in office-based tx
  - Methadone, LAAM, buprenorphine in certified opioid treatment programs

New Treatment options = Increased access to underserved populations

Questions?

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# Federal Guidelines for Opioid Treatment

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# Division of Pharmacologic Therapies

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[www.dpt.samhsa.gov](http://www.dpt.samhsa.gov)

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